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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,958	02/20/2004	Robert S. Whitehouse	098104-0130	4826
48329	7590	10/29/2009		
FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			EXAMINER HAIDER, SAIRA BANO	
			ART UNIT 1796	PAPER NUMBER
			MAIL DATE 10/29/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/783,958

Applicant(s)

WHITEHOUSE, ROBERT S.

Examiner

SAIRA HAIDER

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 81-122 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81-122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 81, 82, 84-111 and 113-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda (US 6,174,990) in view of Saito et. al. (Polymer International).
3. Noda discloses PHA (polyhydroxyalkanoates) are suitable for use as adhesives, in particular Noda recognizes copolymers comprising the claimed 3HB (3-hydroxybutyrate) and 4HB (4-hydroxybutyrate). Noda explicitly discloses using PHA adhesive to join two surfaces. The PHA is applied and then solidifies in order to secure the joint between the surfaces (abstract; col. 6, lines 32-34 and lines 38-40; col. 23, line 53 to col. 25, line 13).
4. However, Noda fails to disclose that the the poly(3-hydroxybutyrate-co-4-hydroxybutyrate) has a glass transition temperature within the claimed range. Thus attention is directed towards the Saito reference which discloses the synthesis of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) (3HB-co-4HB) and measures various properties of the resulting copolymers (abstract). Specifically, when 4HB is present in a mol% of 16, the 3HB-co-4HB has a glass transition temperature of -7°C (Table 5). Saito recognizes these copolymers as displaying various properties, including biodegradability (¶ joining pages 172-173).
5. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the PHA of Saito, the 3HB-co-4HB, in the invention of Noda given that Saito recognizes that PHA as having improved elongation to break and is biodegradable (Table 5). In such substitution, the remaining disclosure of Noda is not modified and only the PHA of Saito is employed, wherein paragraphs 7 to 12 below describe the disclosure of Noda.

6. In reference to claims 111 and 113, drawn to the process of coating the adhesive on the substrate, Noda discloses that the PHA adhesive is applied as a liquid. Noda notes that the adhesives may be applied as solutions, in water or an organic solvent. Wherein the solvent must be removed after application for the adhesive to attain the required solid form; often heating is required to expedite the drying process (thus evaporating the solvent). (col. 23, line 54 to col. 24, lines 5).

7. In reference to claims 88-93, 95, and 97, which are drawn to the amounts of solvent included in the adhesive, Noda states that suitable solid contents of the solutions include from 5% to 95% (col. 24, line 28-30). Accordingly, the suitable solvent content can be calculated to be from 95% to 5%.

8. In reference to claim 96, Noda discloses that the adhesive is formed by dissolving PHA in a suitable solvent (col. 23, lines 63-67). Wherein Noda exemplifies that suitable solvents for dissolving PHAs include chloroform (col. 9, lines 24-26).

9. In reference to the claims 99-102 and 104 additives, Noda discloses formation of a PHA wherein an initiator is included in 6% by weight (Example 1).

10. In reference to claim 114, Noda notes that the heating is conducted by passing the adhesive though the glass transition temperature of one of the components (col. 24, lines 22-26), given that the PHA of Saito has a Tg of -7°C (as noted above), the temperature required for cooling is within the claimed range of at most 40°C.

11. In reference to claims 119-122, regarding pressing a PHA between two surfaces to form the pressed PHA, it is noted that Noda discloses formation of molded articles using PHA. Specifically, Noda discloses blow molding an article by extruding the PHA composition into a closed hollow mold, expanding the mold, cooling to harden the plastic and then opening the mold to remove the article (col. 20, lines 31-37). Suitable pressures to expand the mold include 25-100 psi (col. 20, lines

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38-41). Wherein the PHA copolymer of Saito (the 3HB-co-4HB) has a melting temperature of 130°C (Table 5). So during the blow molding process a temperature of at least 130°C is required, thus meeting the claimed limitation of a temperature of at most 150°C.

12. In reference to claims 85, 118, and 119 which claim a glass transition temperature of about -10°C, it is noted that the term "about" permits some tolerance and Saito reference discloses that the PHA copolymer has a Tg of -7°C. Wherein it is the examiner's position that one skilled in the art would have expected the composition of the Saito reference to have the same properties as the claimed composition. Additionally, a difference of 1-3°C in the glass transition temperature is not expected to change the properties of the composition. It has been held that a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

13. In reference to claims 86 and 87, which are drawn to the inclusion of two different types of PHAs in the adhesive composition, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a mixture of both the PHA disclosed by Saito and the PHA disclosed by Noda in order to obtain an adhesive mixture comprising properties of both components, including, improved elongation to break, as per the PHA of Saito, and increased biodegradability and/or compostability, as per the PHAs of Noda (Noda at col. 4, lines 20-24). Additionally, it is well settled that it is *prima facie* obvious to combine two ingredients, each of which is targeted by the prior art to be useful for the same purpose. *In re Linder* 457 F. 2d 506, 509, 173 USPQ 356, 359 (CCPA 1972).

14. In reference to claim 94, which discloses that the solvent content is at most about 1% by weight, it is noted that the solvent content is recognized as a result effective variable because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In view of this, it would have been obvious to one of ordinary skill in the art to utilize a less than 5% solvent in the adhesive, in particular less than 1% so as to produce desired end results. Wherein utilization of less solvent results in a decreased heating time to remove the solvent and an increase in the thickness of the adhesive layer since more solids are present.

15. In reference to claims 98, which is drawn to the inclusion of two or more solvents, it is well settled that it is prima facie obvious to combine two ingredients, each of which is targeted by the prior art to be useful for the same purpose. *In re Linder* 457 F. 2d 506, 509, 173 USPQ 356, 359 (CCPA 1972). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to include two solvents in the adhesive taught by the combination of Saito and Noda.

16. In reference to claim 103, which discloses that the additive content is at most about 1% by weight, it is noted that the solvent content is recognized as a result effective variable because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In view of this, it would have been obvious to one of ordinary skill in the art to utilize a less than 6% additive in the adhesive, in particular less than 1% so as to produce desired end results. Wherein utilization of less additive (in this case initiator) results in a decrease in the polymerization time,

which may be desired in situations requiring a greater amount of time for application of the adhesive.

17. In reference to claims 105-110 regarding the open time and surface tack time of the adhesive composition, it is noted that since the combination of prior art references teach the identical chemical structures, the properties applicant discloses and/or claims are necessarily present. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical chemical structures, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden shifts to the applicant to show an unobvious difference.

18. In reference to claims 115-117, which claims that different substrate surfaces are coated with the adhesive composition, it is noted that the claims merely modify or change the order of process steps. Noda exemplifies applying the adhesive between the two substrates (Example 19), wherein selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. See MPEP § 2144.04. Since applicant has failed to show unexpected results for the claimed order of applying the adhesive, it is held that the selection of any order, including the claimed order, is prima facie obvious.

19. Claims 83 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda (US 6,174,990) in view of Saito et. al. (Polymer International), as applied above, and in further view of Marecki (US 4,655,768).

20. Saito and Noda apply as discussed above, Noda discloses that the PHA can be utilized as a pressure-sensitive adhesive in bandages (col. 24, lines 62-63). However, the reference fails to

disclose the adhesive layer thickness. Thus attention is directed towards the Marecki reference which discloses bandages having a pressure-sensitive adhesive layer wherein suitable thicknesses include 10 to 150 microns. Marecki notes that the thickness of the adhesive layer has an effect on controlling the rate of dissolution of the drug (col. 3, lines 2-6 and 59-61). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the PHA adhesives taught by Saito and Noda bandages, wherein the thickness of the adhesive layer is within 10 to 150 microns. The motivation is provided by the fact that Noda recognizes the PHAs as suitable for use in bandages and Marecki guides one skilled in the art as to suitable adhesive layer.

Response to Arguments

21. The double patenting rejection has been withdrawn. The remainder of applicant's arguments filed 06/08/2009 have been fully considered but they are not persuasive.
22. Applicant has essentially argued that the claimed 3HB-co-4HB (i.e. PHB4HB) is non-obvious over the teachings of Noda and Saito. Specifically, applicant argues that the PHA of Noda fails to disclose the claimed copolymer of 3HB-co-4HB and that Saito does not teach 3HB-co-4HB having a glass transition temperature between about -30°C to -5°C and good adhesive properties.
23. In response, the obviousness rejection is based on the inclusion of the 3HB-co-4HB of Saito in the invention of Noda.
24. In reference to Noda, the prior art states that when the PHA is an adhesive 50-85% of the RRMUs (monomer units) have the structure of the first RRMU (6:25-27). As noted in the rejection the first RRMU describes both 3HB and 4HB, it is clear that Noda readily envisages a copolymer comprising 85% of 3HB and 4HB. The Saito reference explicitly discloses the claimed 3HB-co-4HB having a glass transition temperature of -7°C, wherein this copolymer in particular displays improved elongation to break as compared to copolymers void of 4HB (Table 5). Wherein the

3HB-co-4HB copolymers in general are recognized by Satio as having biodegradability (paragraph joining pages 172-173). Thus the motivation for the inclusion and utilization of the Satio 3HB-co-4HB copolymer having a glass transition temperature of -7°C in the Noda reference is to utilize a copolymer which displays improved elongation to break and biodegradability. There is a reasonable expectation that the combination of Noda and Satio would be successful because Noda envisages copolymers comprising both 3HB and 4HB.

25. Applicant has argued that Noda fails to disclose that PHA copolymers in general would have adhesive properties. In response, Noda recognizes that a copolymer comprising 85% of the first RRMUs would have adhesive properties. It is not necessary that either reference recognize that PHA's in general or the claimed 3HB-co-4HB possesses such adhesive properties, because a composition and its properties are inseparable. Since the prior art discloses the identical chemical structures, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden shifts to the applicant to show an unobvious difference. Note that because the reference does not expressly disclose or address the properties of the claimed invention, does not mean that the properties are not inherently disclosed. Disclose the same compound(s) inherently discloses the corresponding properties. The references cannot possibly disclose or address all of the properties, but implicitly all of the properties are present.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAIRA HAIDER whose telephone number is (571)272-3553. The examiner can normally be reached on Monday-Friday from 10am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James J. Seidleck/
Supervisory Patent Examiner, Art Unit 1796

Saira Haider
Examiner
Art Unit 1796